Atty. Docket No: 2862 (203-3506 PCT US)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPELLANT: Frank J. Viola

EXAMINER: Rinaldi Rada

SERIAL NO.: 10/529,568

GROUP UNIT: 3721

FILED: March 28, 2005

CONFIRMATION NO.: 9151

FOR: **TOOL ASSEMBLY FOR SURGICAL STAPLING DEVICE**

DATED: March 10, 2008

Mail Stop: Appeal Brief – Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Filed via EFS-Web

REPLY BRIEF

Sir:

This Reply Brief is submitted in response to the Examiner's Answer dated January 8, 2008 that was filed in connection with the above-identified patent application.

Claims 17-27 and 37 stand rejected under 35 U.S.C. § 102(b) over U.S. Patent No. 5,816,471 to Plyley *et al.* (hereinafter "Plyley"). Appellant respectfully submits, however, that Plyley fails to disclose each and every element recited in Claims 17-27 and 37.

Independent Claim 17 recites a tool assembly comprising a pair of jaws including a first jaw and a second jaw, first and second cam followers supported on the first jaw, and an approximation member including at least one cam surface positioned to engage the first and

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Dated: March 10, 2008

Tricia Tucci

second cam followers, "the approximation member being movable through an actuating stroke to move the at least one cam surface in relation to the first and second cam followers" wherein the approximation member is movable "to effect movement of the first jaw to approximate a distal end of the first jaw with the second jaw in a first portion of the actuating stroke, to subsequently move the distal end of the first jaw away from the second jaw in a second portion of the actuating stroke, and to subsequently bring together the first jaw and the second jaw in substantially parallel closure in a third portion of the actuating stroke."

On page 4 of the Examiner's Answer, the Examiner asserts that the device disclosed in Plyley can be moved through the actuating stroke recited in Claim 17 by approximating its jaws in a first portion of the actuating stroke, separating its jaws in a second portion of the actuating stroke and then approximating its jaws once again in a final portion of the actuating stroke.

Column 13, lines 53-64 of the Plyley specification describes the movement of the anvil from the open position to the closed position as follows:

> "The movement of anvil from the open position (FIG. 1) toward the closed position (FIG. 3) is referred to as "tip to tail" closure as initially the leading portion 71 of the anvil moves toward the closed position more rapidly than the trailing portion 73, and then the relative speeds of closure of the leading and trailing portions 71 and 73 are reversed. Preferably, the leading portion 71 reaches a fully closed position prior to the trailing portion 73. This motion is believed to provide desirable clinical results as the initial closure of the distal portion resists extrusion of tissue from between the cartridge retention and anvil portions of the stapler."

As described in the Plyley specification, and discussed on page 10 at lines 1-2 of the Appeal Brief dated October 10, 2007 that was filed in connection with the above-identified patent application, during closure of the Plyley device, the anvil is continuously moving toward the cartridge. While the Examiner's assertion that the jaws of Plyley can be approximated, then

separated, then approximated once again may be accurate, to effectuate such movement, the handle of the device would have to be manipulated more than once, to close the jaws, open the jaws and close them again.

Furthermore, even if one were to use Plyley with multiple actuation strokes as suggested by the Examiner, Plyley would not effectuate closure of the jaws in the manner recited in Claim 17. As indicated above, Plyley describes closure of the jaws at "tip to tail", in that "the leading portion 71 reaches a fully closed position prior to the trailing portion 73." (Col. 13, lines 53-60). In continuously moving the anvil toward the cartridge such that the leading portion 71 of the anvil is closed prior to the trailing portion 73, the anvil constantly defines an angle with the cartridge that is less than 180°. Consequently, the anvil and the cartridge are never brought together "in substantially parallel closure" as recited in Claim 17. Claim 17 recites a specific sequence of jaw movement which Plyley does not disclose.

For at least these reasons, Appellant respectfully submits that Plyley fails to disclose each and every element recited in independent Claim 17, and therefore, that Claim 17 is allowable over Plyley under 35 U.S.C. § 102(b).

At page 4 of the Examiner's Answer, referring to FIGS. 4A-4B of the application, the Examiner argues that the actuating stroke sequence recited in Claim 17 is not suggested and/or shown in the drawings. In particular, the Examiner states that FIGS. 4A-4B illustrate an actuating stroke sequence opposite to the claimed sequence. In response thereto, Appellant directs the Examiner's attention to FIGS. 4A-4C, which are reproduced below for the Examiner's convenience, and page 8 of the specification.

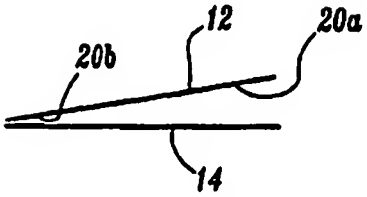

FIG. 4A

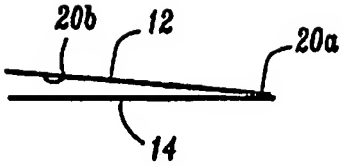

FIG. 4B

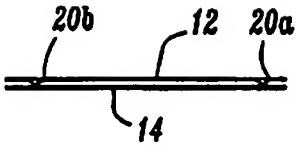

FIG. 4C

The transition illustrated between FIGS. 4A-4B describes pivoting of the anvil "from an open position (FIG. 4A) towards cartridge assembly 14" in the first portion of the actuating stroke such that "the distal end 20a of tissue contact surface 20 of anvil 12 [is] substantially in contact with cartridge 14," (page 8, lines 10-15), the transition between FIGS. 4B-4C illustrates subsequent movement of the distal end 20a of anvil 12 away from cartridge assembly 14 to a resultant position in which tissue engaging surface 20 of anvil 12 is parallel or substantially parallel to tissue engaging surface 25 of cartridge assembly 14 in the second portion of the actuating stroke, (*see* page 8, lines 16-18), which is followed subsequently by the final portion of the actuating stroke in which "the anvil 12 and cartridge assembly 14 are brought together in parallel or substantially parallel closure to define a desired tissue gap," which is seen in FIG. 4C. (Page 8, lines 20-22).

Accordingly, Appellant respectfully submits that the actuating stroke sequence recited in Claim 17 finds sufficient support in both the specification and the figures.

Respectfully submitted,

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